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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,550	09/04/2003	Imtiaz Chaudry	048765/277062	9356

826 7590 12/05/2007

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
12/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/657,550	CHAUDRY, IMTIAZ	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *2, 7-9, 16-21, 31-34, and 36-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 10-15, 22-25, 27-30, 35, and 71-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-25 and 27-74 are pending. Claims 2, 7-9, 16-21, 31-34, and 36-44 are withdrawn as being drawn to a non-elected species. Claims 45-70 are withdrawn as being drawn to a non-elected invention. Applicant has cancelled claim 26. Applicant has amended claims 1, 3, 13-15, 28, 30, and 35. Claims 71-74 are new. **Claims 1, 3-6, 10-15, 22-25, 27-30, 35, and 71-74 are under consideration in the instant office action.** Receipt and consideration of Applicant's amended claim set and remarks/arguments submitted on September 27, 2007 are acknowledged. Applicant's amendments have necessitated new rejections (e.g. under 35 U.S.C. §103(a)).

Moot Rejections/objections

All rejections and/or objections of claim 26 cited in the previous office action mailed on April 23, 2007 **are moot**, because said claim has been cancelled.

Terminal Disclaimer(s)

The terminal disclaimers filed on 9/24/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending applications (1) 11/250,925; (2) 11/078,263; and (3) 11/250,256 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Specification

The objection of claims 3 and 30 because of the informalities set forth in the office action mailed on April 23, 2007 **is withdrawn**, per Applicant's correction of said informalities.

The objection to the specification for the improper use of the trademark THE PHYSICIAN'S DESK REFERENCE® ([0041]) **is withdrawn** per Applicant's amendment of the specification to write the cited trademark in all capital letters.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 71 and 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter). The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not provide support for salts of sodium edetate. It is noted that the specification provides support for salts of editic acid (e.g. sodium edetate) in paragraph [0063]; however, no mention is made of a salt of sodium edetate or how one would prepare and isolate a salt of a salt, such as the complexing agent recited in claims 71 and 73 (i.e. "...sodium edetate or salts thereof"). Thus, the recitation of a complexing agent comprising sodium edetate or salts thereof (emphasis added) is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 1, 3-6, 10-15, 27-28, and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained** for the reasons of record set forth in the office action mailed on April 23, 2007.

Response to Arguments

Applicant's arguments filed 9/24/2007 have been fully considered but they are not persuasive. Applicant has traversed the instant rejection by arguing that the term derivative is allegedly defined in a manner to convey the metes and bounds of what constitutes a fluticasone derivative to an ordinary skilled artisan. The Examiner respectfully disagrees. Applicant's alleged definition in paragraph 32 of the instant application's publication (US 2004/0209852) is not a proper definition, because it merely provides examples of suitable derivatives and does not set forth the metes and bounds of what is a "fluticasone derivative." Thus, the instant rejection remains proper.

Claims 71 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 71 and 73 are confusing, because it is unclear what is a salt of "sodium edetate," because sodium edetate is itself a salt.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1, 3-6, 10-15, 22-25, and 28-30 under 35 U.S.C. 103(a) as being unpatentable over Osbakken et al. (US 2002/0061281) in view of Waldrep et al. (U.S. Patent No. 5,958,378), Lancaster et al. (WO 02/00199; IDS), and Ferrie et al. (WO 01/32125; IDS) **is withdrawn** per Applicant's claim amendments requiring that the composition is an aqueous suspension of solid fluticasone or a derivative thereof.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-6, 10-15, 22-25, and 28-30 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1, 10-15, 22-25, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over FLONASE® from the online Physician's Desk Reference (PDR®), as evidenced by the 1999-2000 Drug Information Handbook (Lacy, C.; Armstrong, L. L.; Armstrong, L. L.; Goldman, M. P.; Lance, L. L., Lexi-Comp, Inc.: Cleveland, 1999, pp 445-446) in view of Bernini et al. (U.S. Patent No. 6,464,958).

Applicant Claims

Applicant claims a formulation comprising (a) 1-700 micrograms of a steroidal anti-inflammatory that is fluticasone or an acceptable derivative thereof characterized by the particle size distribution described in claim 1, further comprising (b) a preservative, such as benzalkonium chloride (e.g. claims 23-24 and 28) and (c) other excipients (e.g. dextrose, carboxymethylcellulose sodium, etc.).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Bernini were set forth in the office action mailed on April 23, 2007. FLONASE® is a commercially available nasal spray sold in a metering, atomizing, spray pump containing therein an aqueous suspension of suspended microfine fluticasone propionate (16 g

bottle delivering 120 individual 50 microgram doses per actuation; i.e. **0.0375% w/w fluticasone propionate**), **microcrystalline cellulose, carboxymethylcellulose sodium, dextrose, 0.02% w/w benzalkonium chloride, polysorbate 80, 0.25% w/w phenylethyl alcohol, wherein the aqueous suspension has a pH between 5 and 7** (PDR printout, pg. 1, "Description section"). The recommended dosage of FLONASE® for adults is 50 micrograms per nostril for a total **daily dosage of 200 micrograms**. Alternatively, the administration of two 100 microgram doses twice daily is also effective. Adolescents and children 4 years of age and older should begin with **100 microgram dosages** (1 spray per nostril per day), but may use 200 micrograms (2 sprays per nostril per day) if not adequately responding (PDR, pg. 7, "Dosage and Administration" section). The DIH demonstrates that FLONASE® was a commercially available product at least in 1999.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

The product information concerning FLONASE® is silent as to the particle size distribution of suspended beclomethasone. The product size distribution is either inherent to FLONASE® or it is obviated by the teachings of Bernini as further articulated below.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It is incumbent on Applicant to demonstrate that the particle size distribution of the suspended fluticasone propionate of FLONASE® is not the same or substantially similar to that claimed by Applicant. It is noted that Applicant has indicated in the specification that there is no

statistical difference between high dose formulations of FLONASE® and Applicant's high dose formulation. However, it is unclear what constitutes a "high dose" of Applicant's formulation and FLONASE®, per Applicant's statement. Applicant's data in Figure 1, for example, also strongly supports the notion that FLONASE® is the same or substantially similar to Applicant's claimed composition, because Applicant's data compared to FLONASE® exhibit the same pattern of fluctuations over a period of 2-14 days; is of a similar magnitude, and in several instances is the same or essentially the same (see, for example, data points at 4, 10, 11, and 13 days). Furthermore, the general differences depicted in Figures 1-4 appear to be merely a difference of degree at best and not a difference of kind. A difference of degree is not sufficient to support patentability. It is noted that Applicant admitted in paragraph 86 of the specification of copending application 10/414,682, which Applicants have incorporated by reference in the instant application, that there was no statistically significant differences between Dey-FP (Applicant's invented composition) and FLONASE® High and Low Dose groups for any efficacy endpoint analysis (relief of signs and symptoms of SAR).

Nonetheless, even if Applicant can demonstrate that the particle size distribution of fluticasone propionate in the claimed composition is not the same as the particle size distribution characterizing the suspended fluticasone propionate of FLONASE®, it would have been prima facie obvious to a person of ordinary skill to modify the particle size distribution of a composition comprising beclomethasone, because it is well known in the art that the particle size distribution of an aerosolized drug composition is very important to the therapeutic efficacy of the drug when delivered by inhalation. It is noted that Bernini teaches aqueous suspensions of beclomethasone having particle size distributions very similar to the particles size distributions

of BDP particles in aqueous suspensions claimed by Applicants The physical characteristics (e.g. size and shape) of particulate compositions are clearly result specific parameters that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal physical particle characteristics (e.g. particle size and/or particle size distribution) of a particulate composition needed to achieve the desired results. It is noted that Bernini stated that suspensions treated with a high-pressure homogenizer (See Example 6) were characterized by remarkably improved nebulization performance. Thus, an ordinary skilled artisan would have been motivated to obtain particles having distributions, such as those taught by Bernini in Table 7 of Example 6, for nebulization to the nasal mucosa, because said suspensions exhibited remarkable nebulization performances and an ordinary skilled artisan would have been able to utilize Bernini's teachings to obtain various particle size distributions with a reasonable expectation of success. Regarding the amounts of suspended steroid, the prior art clearly recognizes that one can increase the dosage of fluticasone or another anti-inflammatory steroid as is necessary to treat a given patient's symptoms. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 3-6, 29-30, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over FLONASE® from the online Physician's Desk Reference (PDR®), as evidenced by the 1999-2000 Drug Information Handbook (Lacy, C.; Armstrong, L. L.; Armstrong, L. L.; Goldman, M. P.; Lance, L. L., Lexi-Comp, Inc.: Cleveland, 1999, pp 445-446) in view of Bernini et al. (U.S. Patent No. 6,464,958) as applied to claims 1, 10-15, 22-25, and 27-28 above, and further in view of Osbakken et al. (US 2002/0061281).

Applicant Claims

Applicant claims a formulation as described above in the instant application further comprising about 0.5 to about 150 mg of an anti-fungal agent (e.g. amphotericin beta) or an antibiotic (e.g. doxycycline).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of FLONASE®, the PDR®, and the DIH were set forth above in the instant office action. The teachings of Bernini and Osbakken were set forth on pages 6-9 (Osbakken) and 12-13 (Bernini) of the office action mailed on April 23, 2007.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

FLONASE® lacks the teaching of further comprising an antifungal agent or an antibiotic. This deficiency is cured by the teachings of Osbakken, which has been provided as a supporting document to show what was known in the art regarding the treatment of rhinitis/sinusitis.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to modify the compositions of FLONASE®/Bernini with the teachings of Osbakken, because it was well-known at the time of the instant invention that sinusitis is a species of rhinosinusitis (i.e. rhinitis) and is an inflammation of one or more membranes of the paranasal sinuses (i.e. paranasal mucosae) can be caused by microbial infection (i.e. fungal or bacterial infection). Using common sense and what was readily known to the ordinary skilled artisan at the time of the instant invention, one would have recognized that the underlying cause of sinusitis or rhinitis could be treated by the inclusion of an anti-microbial agent, such as an anti-fungal agent (e.g. amphotericin beta) or an antibacterial (e.g. doxycycline) in a therapeutically effective dosage. Thus, despite the fact that Osbakken focuses its teachings on aqueous solutions that are filtered, an ordinary skilled artisan would nonetheless have been motivated to modify FLONASE® to incorporate a therapeutically effective amount of an anti-fungal agent and/or an antibacterial to obtain a composition suitable for treating not only the inflammation resulting from an infection, but also suitable for treating the underlying cause of the inflammation (i.e. a fungal and/or bacterial infection). An ordinary skilled artisan would have had a reasonable expectation of success upon modification of the FLONASE®/Bernini composition to further comprise an anti-fungal or antibacterial agent because these are art-recognized therapeutics for treating fungal and bacterial infections and are known in combination with anti-inflammatory steroids. Regarding Applicant's allegation of unexpected results, the Examiner's position related to this allegation is the same as set forth above and is herein

incorporated by reference. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 71-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over FLONASE® from the online Physician's Desk Reference (PDR®), as evidenced by the 1999-2000 Drug Information Handbook (Lacy, C.; Armstrong, L. L.; Armstrong, L. L.; Goldman, M. P.; Lance, L. L., Lexi-Comp, Inc.: Cleveland, 1999, pp 445-446) in view of Bernini et al. (U.S. Patent No. 6,464,958) and Osbakken et al. (US 2002/0061281) as applied to claims 3-6, 29-30, and 35 above, and further in view of Doi (U.S. Patent No. 6,368,616) and Meade (U.S. Patent No. 6,608,054).

Applicant Claims

Applicant claims a formulation as described above in the instant application further comprising a complexing agent (e.g. sodium edetate)

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of FLONASE®, the PDR®, and the DIH were set forth above in the instant office action. The teachings of Bernini and Osbakken were set forth on pages 6-9 (Osbakken) and 12-13 (Bernini) of the office action mailed on April 23, 2007. Doi teaches aqueous suspensions for nasal application and that the compositions may contain additives which are broadly used in nasal drops, such as preservatives, buffers (e.g. **citric acid**), stabilizers, chelating

agents (e.g. **citric acid and editic acid**), pH control agents (e.g. **citric acid**), etc. (title; abstract; col. 2, lines 61-65; col. 3, lines 8-17). The term "chelating agent" is synonymous with "complexing agent." Meade teaches that sodium edetate and citric acid are known complexing agents (col. 9, lines 22-34).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

FLONASE® lacks the teaching of compositions further comprising a complexing agent. This deficiency is cured by the teachings of Doi or Meade, which have been provided as supporting documents to show that complexing agents are conventional ingredients in aqueous nasal formulations.

Finding of Prima Facie Obviousness Rational and Motivation ***(MPEP §2142-2143)***

It would have been prima facie obvious to an ordinary skilled artisan at the time of the instant invention to modify the FLONASE®/Bernini/Osbakken compositions to further comprise a conventional additive broadly used in the formulation of nasal compositions, such as complexing agents. Regarding the specific complexing agent used, an ordinary skilled artisan would have been motivated to utilize any of the well-known complexing agents routinely utilized in aqueous nasal formulations (e.g. EDTA, sodium edetate, citric acid, etc.). An ordinary skilled artisan would have had a reasonable expectation of success, because the addition of complexing agents to aqueous formulations (e.g. nasally administrable aqueous suspensions) is conventional in the art. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to

one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejections on the ground of nonstatutory obviousness-type double patenting of: ***(1)*** claims 1, 10-15, and 22-28 over claims 1, 3-6, 9-20, and 23 of copending Application No. 11/078,263 (copending '263); ***(2)*** claims 1, 10-13, and 22-28 over claims 1, 4, 6-10, 11-14, and 19 of copending Application No. 11/250,256 (copending '256) in view of Bernini et al. (U.S. Patent No. 6,464,958); and ***(3)*** claims 1, 3-6, 10-15 over claims 1-4, 7-8, 10, and 14-19 and 17-30 of copending Application No. 11/250,925 (copending '925) in view of

Bernini et al. (U.S. Patent No. 6,464,958) **are withdrawn** per Applicant's submission of proper terminal disclaimers.

Response to Arguments

Applicant's arguments, see page 30, filed 9/24/07, with respect to the above-mentioned provisional rejections on the ground of nonstatutory obviousness-type double patenting over *(1)* copending Application No. 11/078,263 (copending '263); *(2)* copending Application No. 11/250,256 (copending '256) in view of Bernini et al. (U.S. Patent No. 6,464,958); and *(3)* copending Application No. 11/250,925 (copending '925) in view of Bernini et al. (U.S. Patent No. 6,464,958) have been fully considered and are persuasive. The provisional rejections on the ground of nonstatutory obviousness-type double patenting over *(1)* copending Application No. 11/078,263 (copending '263); *(2)* copending Application No. 11/250,256 (copending '256) in view of Bernini et al. (U.S. Patent No. 6,464,958); and *(3)* copending Application No. 11/250,925 (copending '925) in view of Bernini et al. (U.S. Patent No. 6,464,958) have been withdrawn.

Conclusion

Claims 1, 3-6, 10-15, 22-25, 27-30, 35, and 71-74 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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